CLAIMS:

1. **A method of preparing aggregates of porcine pancreatic islets and porcine Sertoli cells** capable upon implantation into a recipient, of producing insulin in vivo, including or comprising the steps of:

1) isolation of porcine islet cells from the pancreas of donor piglets,

2) isolation of porcine Sertoli cells from the testes of donor piglets,

3) culturing the islet cells together with the Sertoli cells,

4) formation of the aggregates.

2. A method of claim 1 wherein said aggregate is a combination of islet:sertoli cells in a predetermining ratio from 1:20,000 to 1:100;.

3. A method of claim 2 wherein said ratio is between 1:2,000 to 1:4,000.

4. A method of any one of the preceding claims wherein said culturing step is over a time period between 3 to 7 days.

5. A method of claim 4 wherein the time period is for 5 days.

6. A method of any one of the preceding claims wherein said isolation of the islets is followed by purification of the islets.

7. A method of claim 6 wherein the isolation and purification of the islets together comprise or include the steps of:

a) surgical removal,

b) collagenase digestion,

c) washing and culturing of the islets.

8. A method of claim 7 wherein said collagenase digestion involves Liberase H and Xylocaine.

9. A method of any one of the preceding claims wherein said isolation of the Sertoli cells is followed by purification of the Sertoli cells.

10. A method of claim 9 wherein said isolation and purification of the Sertoli cells together comprise or include the steps of:

a) surgical removal,

b) digestion with trypsin, Dnase,

c) washing and culturing of the cells.

11. A method of any one of the preceding claims wherein the method further includes the additional step of:-

5) virological and microbiological testing and/or monitoring of the aggregates and/or components thereof.

12. A method of any one of the preceding claims wherein the method additionally or alternatively includes a prestep before step 1 of virological monitoring and/or testing of one or both of the islets and Sertoli cells.

13. A method of any one of the preceding claims wherein the method additionally or alternatively includes a pre-step of virological monitoring and/or testing of the piglet donors.

14. A method of any one of the preceding claims wherein said islets and Sertoli cells derive from the same herd or from the same donor piglet(s).

15. A method of claim 14 wherein the piglet(s) are about one week old donors.

16. A method of any one of the preceding claims wherein the piglet(s) are monitored and/or tested for infectious agents.

17. A method of any one of the preceding claims wherein said piglet(s) are from a New Zealand pig herd.

18. A method of any one of the preceding claims wherein the step of the formation of the aggregate additionally or alternatively includes the preservation of the original characteristics and/or native structure of the islets.

19. **An aggregate of porcine islets with Sertoli cells** prepared substantially according to a method of any one of claims 1 to 18.

20. A **method of treating a patient suffering from diabetes mellitus** comprising or including the steps of:

1) preparing one or more aggregates of porcine islets with Sertoli cells prepared substantially according to a method of any one of claims 1 to 18,

2) implanting or otherwise administering one or more aggregate to the patient.

21. A method of claim 20 wherein said step of implanting or administering the aggregate may be by:

- encapsulation of the aggregate in a suitable biocompatible material,
- confinement into a suitable device
- matrix preparations including preparation of gelatin, collagen, and natural carbohydrate polymers.
- plasma thrombin clot – autologous plasma clots produced with allogeneic thrombin.

22. A method of claim 21 wherein the biocompatible material is a suitable alginate.

23. A method of any one of claims 21 to 22 wherein the suitable device is a vascularized tube.

24. **A device for implantation** into a recipient suffering from diabetes mellitus, the device incorporating aggregates of porcine pancreatic islets and porcine Sertoli cells, the aggregates being, or possessing the characteristics of, the aggregatesof claim 19..

25. A device of claim 24 wherein said device incorporating the aggregates may be one of:

- a suitable biocompatible material as a capsule;
- a vascularized tube;
- a matrix preparation including preparation of gelatin, collagen, and natural carbohydrate polymers.
- a plasma thrombin clot – autologous plasma clots produced with allogeneic thrombin.

26. A device of claim 25 wherein said biocompatible material is a suitable alginate.

27. **A method of preparing aggregates** of porcine pancreatic islets and porcine Sertoli cells prepared substantially according to Figure 1.

28. An **aggregate** of porcine pancreatic islets and porcine Sertoli cells substantially as described herein and with reference to any one or more of Figures 1 to 5.